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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,165	04/16/2004	Jiro Kanie	889_001	8549
25191	7590	11/16/2007		
BURR & BROWN PO BOX 7068 SYRACUSE, NY 13261-7068			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,165	Applicant(s) KANIE, JIRO	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/07 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,4,6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ying et al (**Quick Chocolate-Almond Mousse** recipe entry page 530, *The New Good Housekeeping Cookbook*). The claims are drawn to a formulation comprising a liquid nutrient and a solidifying agent.

4. The Ying recipe calls for about 1 1/4 cup of milk (nutrient liquid) and 1 whole egg (solidifying agent) to be mixed together in a blender (step 2). The mixture is blended until smooth and then chilled before serving in order to stiffen and become more self-sustaining (step 3). The approximately 1 cup of milk measures to 250 mL depending on the cup used, whether a U.S, UK or metric measuring cup is used for the recipe.

Art Unit: 1618

5. Regarding the enteral, non-oral administration limitations, it is the position of the Examiner that such limitations are merely an intended use and do not impart patentability on the claims. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).
6. Regarding product claim 4, which recites process limitations, it is the position of the Examiner that these limitations do not impart any patentability to the claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)
7. These disclosures render the claims anticipated.
8. Claims 1,3,4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ying et al (**Rice Pudding**; recipe entry page 542, *The New Good Housekeeping Cookbook*). The claims are drawn to a formulation comprising a liquid nutrient components and a solidifying agent. The claims a method of making the formulation comprising mixing the liquid and solidifying agent, followed by heating the mixture.

Art Unit: 1618

9. The Ying recipe calls for 4 cups of milk (nutrient liquid) and 2 whole eggs (solidifying agent). The recipe requires the eggs to be mixed into the milk in a saucepan (holder) and heated (step 2). The resulting pudding is self-sustaining yet smooth and pliable (step 2).

10. Regarding the enteral, non-oral administration limitations, it is the position of the Examiner that such limitations are merely an intended use and do not impart patentability on the claims. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

11. Regarding product claim 4, which recites process limitations, it is the position of the Examiner that these limitations do not impart any patentability to the claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

12. For these reasons the disclosures of the recipe anticipate the claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1618

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ying et al (*Rice Pudding*; recipe entry page 542, *The New Good Housekeeping Cookbook*) in view of Kabushiki et al (*Total Parenteral Nutritional and Enteral Nutrition*, pg 283-307, Suppl. 5, *Nippon Rinsho*, vol. 59, no. 782). The claims are drawn to a formulation for enteral administration comprising a nutritional liquid and a solidifying agent; wherein the mixture is fed through a feeding tube of predetermined internal diameter.

16. As discussed above the Ying recipe provided a sufficiently self sufficient and stable pudding recipe comprising a nutritional liquid (milk) and a solidifying agent (eggs). The reference is silent to a specific enteral or parenteral administration yet the formulation, being a good course of calcium and low in sodium would be an obvious inclusion in a direct feed administration. Such compositions are used in the Kabushiki reference.

17. The Kabushiki reference discloses an enteral feeding method. The device administers thick fluid diets such as puddings or crèmes, using feeding tubes with internal diameters larger than 4 mm (diagram). It would have been obvious to use the pudding recipe of Ying in the feeding tube method described by Kabushiki since it would provide a diet high in calcium and

Art Unit: 1618

low in sodium to a patient in need. Also the tubing of the Kabushiki patent would provide an even flow to the thick composition avoiding air-bubbles that would adversely affect the patient.

18. With these things in mind it would have been obvious to combine the rice pudding of the Ying recipe into the enteral administration device of the Kabushiki reference in order to provide an enteral formulation high in calcium to a patient in need thereof. One of ordinary skill in the art would have been motivated to combine these disclosures with an expected result of an enteral feeding composition with a smooth even rate of flow directly to the intestine.

19. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Carlsson et al (USPN 5,716,639 hereafter '639). The claims are drawn to a formulation comprising a nutrient liquid and a solidifying agent where the solidifying agent is agar.

20. The '639 patent teaches a lipophilic carrier preparation comprising agar and other nutrients in order to make cosmetic or food emulsions (abstracts). The aqueous solution used to make the emulsion of the invention comprises thickeners such as agar (col. 4, lin. 34-40). The lipophilic carrier is derived from natural sources such as oats making it a nutrient liquid (examples). The formulation further comprises water as a diluting agent (col. 4, lin. 35). The formulation can be delivered orally, enteral or by any other means well known in the art (col. 5, lin. 8-11, lin. 25-32). The patent establishes the knowledge in the art of using agar as a thickening agent, in enteral emulsions.

21. Regarding the specific amount of agar relative to the diluting liquid, it is the position of the Examiner that these limitations do not impart patentability to the claims. The general

Art Unit: 1618

conditions of the claims have been met by the '639 patent. The water-in-oil emulsion comprises water (a diluting liquid), a thickening agent and a nutrient liquid mixture (example 8). Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

22. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

23. With these things in mind it would have been obvious to follow the suggestions of the '639 patent in order to provide a stable enteral formulation that can also act as a carrier for pharmaceutical agents. One of ordinary skill in the art would have been motivated to follow these teachings and suggestions with an expected result of a stable enteral formulation capable of provided delivery of pharmaceutical agents.

Response to Arguments

24. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1618


Correspondence

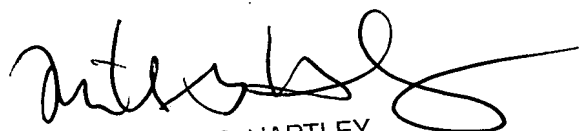
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER